**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF PENNSYLVANIA**

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| SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN; MC - UA LOCAL 119 HEALTH AND WELFARE PLAN; A.F. OF L. - A.G.C. BUILDING TRADES WELFARE PLAN; IBEW - NECA LOCAL 505 HEALTH & WELFARE PLAN; UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND; SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER, INC.; EILEEN JACOBS; LARA KECK; MATTHEW ANDRE; and HEALTH CARE FOR ALL, INC., on behalf of themselves and all others similarly situated,<br><br>Plaintiffs,<br><br>v.<br><br>GLAXOSMITHKLINE, plc; and SMITHKLINE BEECHAM CORPORATION,<br><br>Defendants. | Civil Action No.: |

**CLASS ACTION COMPLAINT**

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Plaintiffs identified in paragraphs 7-16 herein ("Plaintiffs"), on behalf of themselves and all others similarly situated, hereby seek damages, other monetary relief and equitable relief for Defendants' violations of federal and state antitrust laws, state consumer protection laws and state common law principles of unjust enrichment. Plaintiffs allege, upon knowledge as to themselves and their own acts, and upon information and belief as to all other matters, as follows:

## INTRODUCTION

1. This litigation arises from a series of actions undertaken by Defendants GlaxoSmithKline plc, and SmithKline Beecham Corporation to unlawfully maintain their monopoly on Wellbutrin SRR ("Wellbutrin SR") and/or Zyban®. Faced with the threat of losing market exclusivity, Defendants engaged in a series of anticompetitive, and unlawful actions that ultimately extended exclusivity on the sale of Wellbutrin SR and Zyban.

2. Wellbutrin SR is a sustained release antidepressant drug used to treat depression. The active ingredient in Wellbutrin SR is bupropion.[1] Zyban, which has the same chemical composition as Wellbutrin SR, is marketed and sold by Glaxo for the cessation of smoking. For the 12 months ending June 30, 2002, domestic sales of Wellbutrin SR generated revenues in excess of $1.3 billion. Domestic sales of Zyban were $83 million during the same period.

3. At least five manufacturers of generic drugs, including Eon Labs Manufacturing ("Eon"), Andrx Pharmaceuticals ("Andrx"), Watson Pharmaceuticals ("Watson"), IMPAX Laboratories ("IMPAX"), and Excel Pharmaceuticals ("Excel") filed applications with the FDA

[1] Wellbutrin and Zyban are the same medication and are covered by the same patent, but, as stated above, are marketed for different indications -- antidepression and smoking cessation, respectively. Accordingly, generic pharmaceutical manufacturers seeking to sell generic versions of sustained release bupropion for treatment of depression also seek approval to sell generic versions of Zyban.

requesting approval to market generic versions of Wellbutrin SR and/or Zyban. In their applications, the manufacturers assert that their products are "bioequivalent" to Wellbutrin SR and Zyban and do not infringe any patent owned by or licensed to Defendants. Because of Defendants' actions, however, certain of these generic formulations were unlawfully delayed from coming to market.

4. Defendants unlawfully extended their monopoly in the United States Wellbutrin SR/Zyban markets by filing baseless patent infringement actions against manufacturers seeking to market generic versions of Wellbutrin SR and/or Zyban. As a result of their unlawful acts, Defendants have: (i) unreasonably restrained, suppressed and eliminated competition in the Wellbutrin SR and Zyban markets; and (ii) illegally maintained a monopoly in the Wellbutrin SR and Zyban markets. Plaintiffs bring their claims on behalf of all indirect purchasers of Wellbutrin SR and/or Zyban, *i.e.* consumers and third-party payors, the last persons and entities in the chain of distribution, who purchased these prescription drugs other than for resale from July 1, 2001 to the present (the "Class Period").

5. Defendants' conduct has had far-ranging impact on consumers and third-party payors across the United States. The laws governing approval and marketing of pharmaceutical products are meant to balance the competing policy goals of providing new drug innovators an economic return on their investments while also ensuring consumers access to additional and more affordable generic versions of brand-name drugs. By engaging in anticompetitive conduct to prevent generic entry, Defendants effectively forced consumers to continue paying monopoly prices for Wellbutrin SR and/or Zyban prescription products.

6. As a direct and proximate result of Defendants' unlawful conduct, consumers and third-party payors throughout the United States have been denied the benefits of free and

unrestrained competition in the Wellbutrin SR and Zyban markets. Specifically, purchasers have been denied the opportunity to choose between the Wellbutrin SR and Zyban brand name prescription products and generic versions of these medications which would have been priced well below Wellbutrin SR and/or Zyban.

## THE PARTIES

### Third-Party Payor Plaintiffs

7. Plaintiff Sheet Metal Workers Local 441 Health & Welfare Plan (the "Sheet Metal Workers Plan") is a welfare benefit plan with its principal place of business in Mobile, Alabama. The Sheet Metal Workers Plan represents participants who have family coverage and purchased or paid for Wellbutrin SR and Zyban. During the Class Period, the Sheet Metal Workers Plan and its members were indirect purchasers of Wellbutrin SR and/or Zyban and were injured by Defendants' unlawful conduct as alleged.

8. Plaintiff MC - UA Local 119 Health and Welfare Plan (the "UA Plan") is a welfare benefit plan with its principal place of business in Mobile, Alabama. The UA Plan represents participants who have family coverage and purchased or paid for Wellbutrin SR and Zyban. During the Class Period, the UA Plan and its members were indirect purchasers of Wellbutrin SR and/or Zyban and were injured by Defendants' unlawful conduct as alleged herein.

9. Plaintiff A.F. of L. - A.G.C. Building Trades Welfare Plan (the "AFL Plan") is a welfare benefit plan with its principal place of business in Mobile, Alabama. The AFL Plan represents participants who have family coverage and purchased or paid for Wellbutrin SR and Zyban. During the Class Period, the AFL Plan and its members were indirect purchasers of Wellbutrin SR and/or Zyban and were injured by Defendants' unlawful conduct as alleged.

10. Plaintiff IBEW - NECA Local 505 Health & Welfare Plan (the "IBEW Plan") is a welfare benefit plan with its principal place of business in Mobile, Alabama. The IBEW Plan represents participants who have family coverage and purchased or paid for Wellbutrin SR and/or Zyban. During the Class Period, the IBEW Plan and its members were indirect purchasers of Wellbutrin SR and/or Zyban and were injured by Defendants' unlawful conduct as alleged.

11. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") is an "employee welfare benefit plan" and "employee benefit plan." UFCW's office from which it pays medical benefits, including benefits for prescription drugs, is located in Cook County, Illinois. During the Class Period, the UFCW Plan and its members were indirect purchasers of Wellbutrin SR and/or Zyban and were injured by Defendants' unlawful conduct as alleged.

12. Plaintiff Sidney Hillman Health Center of Rochester, Inc., is a multi-employer employee welfare benefit plan. During the Class Period, the Sidney Hillman Health Center was an indirect purchaser of Wellbutrin SR and/or Zyban and was injured by Defendants' unlawful conduct as alleged herein.

**Consumer Plaintiffs**

13. Plaintiff Eileen Jacobs purchased Wellbutrin SR and/or Zyban during the Class Period and, like the other members of the Class, paid more than she would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Wellbutrin SR and/or Zyban.

14. Plaintiff Lara Keck purchased Wellbutrin SR and/or Zyban during the Class Period and, like the other members of the Class, paid more than she would have absent

Defendants' unlawful monopolization and attempts to restrict generic access for Wellbutrin SR and/or Zyban.

15. Plaintiff Matthew Andre purchased Wellbutrin SR and/or Zyban during the Class Period and, like the other members of the Class, paid more than he would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Wellbutrin SR and/or Zyban.

**Public Interest Organization Plaintiffs**

16. Plaintiff Health Care For All, Inc. ("HCFA") is a Massachusetts private non-profit membership corporation organized under Chapter 180 of the Massachusetts laws with its principal place of business in Boston, Massachusetts. Founded in 1985, HCFA represents about 1,200 dues paying members, and seeks healthcare reform through policy analysis, information referral, advocacy, community organization and public education. Certain HCFA members purchased Wellbutrin SR and/or Zyban other than for resale and were injured by the illegal conduct alleged herein.

**Defendants**

17. GlaxoSmithKline plc is a United Kingdom corporation with its principal offices located at Glaxo Wellcome House, Berkeley Avenue, Grenford, Middlesex, UB6 0NN, United Kingdom. GlaxoSmithKline was formed following the December 2000 merger of Glaxo Wellcome and SmithKline Beecham.

18. SmithKline Beecham Corporation is a Pennsylvania Corporation with its principal offices located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham also conducts business in the name of GlaxoSmithKline Inc. and is a subsidiary of GlaxoSmithKline plc (GlaxoSmithKline plc and SmithKline Beecham Corp. d/b/a GlaxoSmithKline Inc. are referred to collectively as "Glaxo").

## JURISDICTION AND VENUE

19. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive relief, and the costs of suit, including reasonable attorneys' fees, for injuries to Plaintiffs and members of the class resulting from, *inter alia*, Defendants' violations of the federal antitrust laws. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, 1337, 1338(b) and 15 U.S.C. § 26. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a).

20. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) because Defendants reside, transact business, are found, and/or have agents in this district, and because a substantial portion of the affected trade and commerce described below has been carried out in this district.

## CLASS ACTION ALLEGATIONS

21. Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, specifically Rules 23(b)(2) and 23(b)(3), on behalf of the following class (the "Class"):

> All persons and entities in the United States who, at any time from July 1, 2001 to the present purchased Wellbutrin SR, Zyban and/or their generic equivalents in the United States for purposes other than resale. Excluded from the Class are the Defendants, their subsidiaries and affiliates, government entities and any person or entity that purchased Wellbutrin SR and/or Zyban directly from Defendants. For purposes of the Class definition, persons and entities "purchased" Wellbutrin SR and/or Zyban if they paid some or all of the purchase price.

22. Plaintiffs believe, and therefore aver, that there are thousands of members in the above-described class; their exact number and identities being currently unknown to Plaintiffs, but known to Defendants and/or ascertainable from appropriate discovery.

23. Among the questions of law and fact common to the Class are:

(a) Whether Defendants have unlawfully monopolized or attempted to monopolize the market for Wellbutrin SR and/or Zyban;

(b) Whether Defendants possessed and/or unlawfully extended their monopoly power over the market for Wellbutrin SR and/or Zyban;

(c) Whether Defendants, through their monopolization and/or attempted monopolization, have caused the prices of Wellbutrin SR and/or Zyban to be maintained at supracompetitive levels;

(d) Whether Defendants' patent infringement lawsuits against Eon and IMPAX to prevent them from entering the market with a lower priced therapeutically equivalent version of Wellbutrin SR and/or Zyban constitutes unlawful conduct;

(e) Whether the Class suffered antitrust injury; and

(f) Whether Defendants were unjustly enriched to the detriment of the Class, entitling Plaintiffs and the Class to disgorgement of all monies resulting therefrom.

24. Plaintiffs' claims are typical of the Class because Plaintiffs and all members of the Class were injured in the same manner by Defendants' unlawful, anticompetitive and inequitable methods, acts and practices, and wrongful conduct complained of herein, *i.e.,* they have paid supra-competitive and artificially high prices for Wellbutrin SR and/or Zyban.

25. Plaintiffs will fully and adequately protect the interests of all members of the Class. Plaintiffs have retained counsel who are experienced in antitrust class action litigation. Plaintiffs have no interests which are adverse to, or in conflict with, other members of the Class.

26. The questions of law and fact common to the members of the Class predominate over any questions which may affect only individual members.

27. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The Class is readily definable and prosecution as a class action will eliminate the possibility of duplicative litigation, while also providing redress for claims which would otherwise be too small to support the expense of individual, complex litigation.

28. Defendants have acted or refused to act, as alleged herein, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief and/or corresponding declaratory relief with respect to the Class as a whole.

## FACTUAL ALLEGATIONS

29. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. In 2001, sales of prescription drugs dispensed in the United Sates were approximately $153 billion.

30. In recent years, sales of Wellbutrin SR and Zyban have generated billions in revenues for Defendants most of which was unlawfully obtained by Defendants' unlawful suppression of generic equivalents.

### A. The Federal Scheme For Approval Of Pioneer Drugs

31. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. (the Act"), approval by the FDA is required before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "branded" drug, must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, codified at 21 U.S.C. § 355(j) (the "Hatch-Waxman Act") and 35 U.S.C. § 271(e).

32. In addition to information on safety and efficacy, NDA applicants must submit to the FDA a list of all patents that claim the drug for which FDA approval is being sought, or that

claim a method of using that drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

33. Once the NDA is approved, the FDA lists any patents referenced as part of the NDA application process in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), where it can be easily found and consulted by future FDA applicants.

34. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer drug manufacturer obtains a new patent that claims the drug or methods of its use, the company must supplement its NDA by submitting information on the new patent within 30 days of issuance. The FDA then lists the new patent in a supplement to the Orange Book. The FDA is required to accept as true the patent information it obtains from patent holders, and to withhold its approval of a subsequent drug application, whenever the patent holder presents a litigated dispute (baseless or not) regarding the validity or infringement of the patent. If an unscrupulous patent holder provides false information to the FDA or files frivolous patent infringement actions to delay the onset of generic competition, the FDA is powerless to stop it.

35. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug that has been approved by the FDA is available.

**B. Generic Drug Entry**

36. Generic drugs are drugs that the FDA has found to be bioequivalent to brand name drugs, *i.e.*, generic drugs have the same active chemical composition and provide the same

therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

37. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and quickly takes a substantial amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generic equivalents continues to fall, and their combined market share continues to grow. In some cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 15% of the price of the brand-name drug, and have captured as much as 90% of the brand-name drug's pre-generic sales. Unless the branded manufacturer lowers prices to meet competition, a branded drug loses a significant portion of its market share to generic competitors less than a year after the introduction of generic competition.

38. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing either the branded drug, or the AB-rated generic at a lower price.

39. Once a physician writes a prescription for a brand-name drug such as Wellbutrin, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs that carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

40. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, who are able to buy the same chemical substance at much lower prices. Many health insurance companies and employee benefit plans encourage or require substitution of generic drugs for brand-name drugs in order to lower health care costs. Retail pharmacies routinely substitute generic drugs for brand-name drugs whenever possible in order to lower their own costs and the costs of their customers.

### C. Abbreviated New Drug Applications For Generic Drugs

41. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development, approval and marketing of generic drugs. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an "abbreviated" new drug application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted to the FDA by the company that manufactured the original, "pioneer" drug. The Act also provides an economic incentive to the manufacturer of the first generic drug to file an ANDA for a particular generic drug – *i.e.*, a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its drug free from other generic competition.

42. The most important new information that must be included in the ANDA concerns the generic company's position vis-a-vis the patent that the pioneer manufacturer claims applies to the drug. Therefore, the ANDA filer must make one of four certifications to the FDA:

I. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

II. that the patent (or patents) for the pioneer drug has (or have) expired (a "Paragraph II Certification");

III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV certifications. *See id.* If the generic manufacturer makes a Paragraph IV Certification, the ANDA applicant must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vi)(IV).

43. The patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has a 45-day statutory period in which to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If no action is initiated within 45 days, FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the generic drug is automatically postponed until the earliest of: (i) the expiration of the patent; (ii) thirty months from the patent holder's receipt of the Paragraph IV Certification (30-month stay); or (iii) a final judicial determination of invalidity or non-infringement from which no appeal can be or has been taken. *Id.*; 21 C.F.R. § 314.107.

44. At all times relevant herein, under 21 U.S.C. § 355(j)(5)(B)(iv), the first applicant to submit an acceptable ANDA with a Paragraph IV Certification for a generic version of a brand-name drug receives a 180-day period of exclusivity before other ANDAs for the same drug can be approved by the FDA. The 180-day exclusivity period begins when the first ANDA applicant either (a) begins selling the generic drug or (b) obtains a final judgment of non-

infringement in a patent infringement action, whichever occurs first. Thus, the first generic ANDA applicant has the opportunity to compete directly with the brand-name manufacturer for 180 days without competition from other generic manufacturers. If, however, the patent holder is able to forestall the events which trigger the start of the 180-day period of exclusivity, it can delay indefinitely the entry of all generic competitors.

**D. The Development of Wellbutrin SR And Zyban**

45. Bupropion hydrochloride is an antidepressant used in the treatment of depression that is no longer subject to an extant patent. On June 25, 1974, the United States Patent and Trademark Office issued U.S. Patent No. 3,819,706 (the " '706 Patent"), granting to a predecessor of Defendants a compound patent on bupropion.

46. In the mid-1980s, the FDA granted to Defendants' predecessor approval to manufacture, market and sell bupropion hydrochloride under the brand name Wellbutrin. Defendants' predecessors, thereafter, began the manufacture, marketing and sale of Wellbutrin.

47. At that time, bupropion hydrochloride, or Wellbutrin, was sold in the form of an instant release tablet in which more than 75% of the bupropion was released from the tablet into dissolution media within about forty-five minutes. It was generally prescribed to be taken three or four times per day.

48. The '706 Patent expired in mid-1991. By that time, and for years before then, Defendants' predecessors had enjoyed a monopoly on the sale of bupropion through the manufacture, marketing and sale of Wellbutrin.

**(i) The 1993 Sustained Released HPMC Patent Application**

49. Subsequent to expiration of the '706 Patent, Defendants developed a sustained release version of bupropion which it markets as Wellbutrin SR. This formulation allows users of the drug to treat depression with only one or two daily doses.

50. In August 1993, Defendants' predecessor filed an application with the United States Patent and Trademark Office ("PTO") seeking patent protection for a controlled sustained release tablet containing bupropion (the "1993 SR Application").

**(ii) Prosecution of the 1993 SR Application**

51. The prosecution of the 1993 SR Application made evident the need for all claims to focus on, and be limited by, the significant role that hydroxypropyl methylcellulose ("HPMC") played in the invention.

52. On April 13, 1994, the examiner rejected Claims Fourteen, Fifteen and Nineteen of the Application for lack of enablement. Specifically the examiner wrote:

> The rate of release is directly related to the release retarding effect of hydroxypropyl methylcellulose. While other excipients have been disclosed, *the particular cellulose is considered critical for controlled and/or sustained release and should be incorporated into the independent claims.* The disclosure of a single species does not provide a basis for disclosing a generic concept . . . . (Emphasis added.)

53. In response, Defendants amended Claims Fourteen and Fifteen to recite that the tablets required HPMC. Defendants failed to amend Claims Eighteen and Nineteen at that time, but these claims were later amended by the examiner to identify the use of HPMC as the means for releasing bupropion.

54. Moreover, Defendants' proposed Claim One in the 1993 Application did not contain any recitations regarding bupropion release. The examiner, therefore, rejected this Claim for lack of enablement as well, noting that the claim needed to be limited:

> [A]pplicants are claiming a tablet that provides a distinct release profile. The advantage provided by the unique tablet *differ [sic] from the instant release tablet. The limitations of claims 2-3 are considered critical and should be incorporated into claim 1 for proper enablement*. (Emphasis added.)

55. In response, Defendants made similar amendments to Claim One, limiting it with the release controlling language.

56. The examiner's initial assessment of the 1993 SR Application was that the prior release controlling language in Claims One, Fourteen, Fifteen, Eighteen and Nineteen was too broad. By amending these claims (and indeed, by being forced to amend these claims), Defendants acknowledged and conceded that HPMC was the "particular cellulose that is critical for the controlled release of the tablets."

57. The PTO later mailed an Examiner's Amendment, which was authorized by counsel for Defendants, adding an HPMC limitation to another two claims in the '798 Patent. The PTO also issued a Notice of Allowability, signifying that the PTO's previous rejection of the claims would be withdrawn based on the addition of the HPMC limitation.

**(iii) Issuance of the '798 Patent**

58. Based on the prosecution history, including the examiner's analysis and the compulsory amendments, it was clear that the ultimate patent would cover HPMC as a control release agent.

59. On June 27, 1995 -- after the claims in the 1993 SR Application had been limited during patent prosecution -- the PTO issued Patent No. 5,427,798 (the " '798 Patent") entitled "Controlled sustained release tablets containing bupropion." The '798 Patent was issued to Defendants' predecessor.

60. Glaxo describes the sustained release tablet claimed in the '798 Patent as follows:

> A controlled sustained release tablet having at least one year shelf life and containing bupropion hydrochloride, hydroxypropyl methylcellulose and cysteine hydrochloride or glycine hydrochloride with the tablet having a surface area to volume ratio to effectively control bupropion hydrochloride release in the body.

61. The patent specifications and patent prosecution history make clear that the '798 Patent is a narrow patent claiming a specific form of extended release tablet of bupropion which incorporates the excipient hydroxypropyl methylcellulose ("HPMC") as a control release agent.

62. Also clear both from the nature of the claims made in the '798 Patent, as well as from the patent prosecution history, is that HPMC as a release control agent is critical to the sustained release technology claimed by the '798 Patent.

63. Indeed, in its "*Brief Statement of Invention*," Glaxo notes that the purpose for the presence of HPMC is for "controlling drug release rate."

64. Glaxo knew that hydroxypropyl cellulose had been recognized as a release controlling substitute excipient for HPMC when the patent application was filed and the '798 patent was issued. Glaxo also knew when this patent application was filed that polyvinyl alcohol could be used as a controlled released excipient.

65. After limiting its claims, Glaxo could not broadly enforce the patent beyond the limitations established during the prosecution history. Under the legal doctrine of Prosecution History Estoppel or File Wrapper Estoppel, a patentee is not able to recapture subject matter surrendered during prosecution of the patent by claiming that the surrendered material is an equivalent of the patented invention.

**(iv) Wellbutrin SR and Zyban Go To Market**

66. In October of 1996, the FDA granted final approval for Wellbutrin SR, and Defendants sought protection for the product by listing, among other things, the '798 Patent in the Orange Book. In Febuary of 1997, Defendants began marketing 50 mg, 100 mg and 150 mg dosages of Wellbutrin SR.

67. In May of 1997, the FDA granted final approval for Zyban, and Defendants sought protection for the product by listing, among other things, the '798 Patent in the Orange Book. Later that year, Defendants began marketing 150 mg dosages of Zyban.

### E. Unlawfully Supressed Generic Competition For Wellbutrin and Zyban

#### (i) ANDAs Submitted For Approval to Market Generic Versions of Wellbutrin SR and Zyban and the Patent Infringement Actions

68. Several manufacturers of generic drugs filed ANDAs with the Food and Drug Administration seeking authorization to market generic versions of Wellbutrin SR. These companies include Andrx, Watson, Eon, IMPAX, and Excel.

69. While the patent claiming bupropion expired more than ten years ago, the '798 Patent claiming bupropion with HPMC in a sustained release formulation is still in effect.

70. Because utilization of the sustained release technology patented by Glaxo would constitute infringement of the '798 Patent, the above-referenced generic drug manufacturers have sought approval to market generic versions of Wellbutrin SR that utilized different sustained release formulations.

71. Eon, Excel, Impax and Watson sought approval of a bupropion sustained release tablet that does not use HPMC as a control release agent and, therefore, would not infringe upon any valid patent.

72. On June 18, 1999, Andrx submitted an ANDA for Wellbutrin SR 100 mg. market as well as for Zyban. The FDA rejected the application insofar as it pertained to the market on the ground the application lacked safety information pertaining to Eudragit E 100.

73. In late July, 1999, the FDA informed Andrx that its ANDA application was not accepted for filing and requested additional information concerning the safety of Eudragit E 100. Before Andrx could submit the requested information, Watson submitted an ANDA for the Wellbutrin and Zyban which was accepted by the FDA, thereby making Watson the first filer for

the Wellbutrin and Zyban markets and entitling it to the 180 day exclusivity period afforded by the Hatch-Waxman Act.

74. Approximately 12 days after Watson submitted its ANDA application, Andrx submitted an amendment to its ANDA with the required safety information on Eudragit E 100. On August 27, 1999, the FDA informed Andrx of the acceptance of its ANDA as of the date of its August 12, 1999 filing.

**(ii) The Infringement Actions and the Watson Litigation**

75. The filing of a patent infringement action triggers a 30-month stay on the sale of generic versions pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay is triggered irrespective of whether there is any likelihood of success, or even merit, to the patent infringement action.

76. Defendants instituted a series of patent infringement actions that are objectively baseless and without merit for the purpose of triggering the 30-month stay and extending the time during which they enjoy complete exclusivity in the domestic market for Wellbutrin SR and Zyban.

77. Glaxo has aggressively prosecuted the patent infringement actions in seeking to maintain their hold on the Wellbutrin SR market.

78. Defendants' lawsuits pressed the scope of the '798 Patent. In commencing these actions, Defendants ignored the express limitations that they knew had been imposed by the PTO in order to obtain issuance of the '798 patent. Defendants knew that litigation against the potential generic entrants was ultimately likely to fail.

79. Watson was the first-filer of an ANDA for 100 mg. sustained-release bupropion hydrochloride.

80. Glaxo received notice of Watson's ANDA on October 26, 1999 and filed a patent infringement lawsuit against Watson on December 2, 1999.

81. A year and a half later, Glaxo settled its patent infringement lawsuit against Watson in July 2001. Documents relating to the settlement and/or discontinuation of the action were filed under seal and are not publicly available.

82. Following the settlement with Glaxo, Watson relinquished its exclusivity rights to the 100 mg. dosage of sustained-release bupropion hydrochloride.

**(iii) The Eon ANDA and Patent Litigation**

83. In July 2000, Eon submitted ANDA 75-932 seeking FDA approval to sell generic versions of Wellbutrin SR and Zyban.

84. Eon's ANDA included a Paragraph IV Certification with regard to the '798 Patent claiming that its medication did not infringe on Glaxo's patent.

85. Eon's Paragraph IV Certification of non-infringement was predicated on the fact that its bupropion sustained release tablet did not utilize the HPMC release technology patented by Glaxo, but rather contained hydroxypropyl cellulose ("HPC") as a control release agent.

86. On November 29, 2000, Glaxo sued Eon in the Southern District of New York claiming that Eon's generic Wellbutrin SR infringed two of its patents.

87. On February 13, 2003, the United States District Court for the Southern District of New York held on reconsideration that fact issues exist as to whether Glaxo was estopped from asserting infringement under the doctrine of equivalents. The court again denied Glaxo's summary judgment motion.

88. On August 22, 2003, the United States District Court for the Southern District of New York granted Eon summary judgment finding claim 1 of the '798 Patent invalid for lack of

specificity and denied summary judgment as to the allegation that the entire patent is invalid by reason of overbroadness.

89. Notably on January 24, 2002, during the pendency of the litigation, Eon received tentative approval by the FDA to market its generic version of Wellbutrin SR and Zyban utilizing the HPC sustained release formulation. Eon received final approval to enter the market on November 26, 2003.

90. Eon eventually received final approval in November, 2003 to market its bioequivalent generic version of Wellbutrin SR and Zyban in the United States. But for the unlawful conduct of Defendants, Eon would have been able to market, distribute and sell a generic equivalent of Wellbutrin and Zyban at least as early as July 1, 2001. The unlawful conduct includes the filing of baseless lawsuits seeking to enjoin the generic manufacturers from producing bioequivalent generic versions of Wellbutrin SR and/or Zyban on the grounds that these generics infringe upon Defendants' patents.

91. Eon did not enter the market until January 27, 2004. The delay of at least two years for the entry of a generic equivalent for Wellbutrin and Zyban was directly and proximately the result of the unlawful conduct of Defendants.

**(iv) The IMPAX ANDA and Patent Litigation**

92. In August 2000, IMPAX Laboratories submitted an ANDA seeking FDA approval to sell generic versions of Wellbutrin SR and Zyban.

93. Like Eon's ANDA, IMPAX's ANDA included a Paragraph IV Certification with regard to the '798 Patent which was predicated on the fact that IMPAX's proposed bupropion sustained release tablet utilized HPC as a control release agent, not HPMC.

94. On September 28, 2000, Glaxo sued IMPAX in the Northern District of California for infringement of its '798 Patent.

95. At the time Glaxo commenced the patent infringement action against IMPAX, it was aware, as it was at the time the '798 patent application was filed, that: (i) HPC had been recognized as a release controlling substitute excipient for HPMC; and (ii) by narrowing the patent claims during the prosecution, Glaxo abandoned any subject matter that existed between the original and amended claims.

96. IMPAX countered by arguing that its product did not use the HPMC sustained release technology patented by Glaxo, and moved for summary judgment on the grounds that the prosecution history precluded Glaxo from trying to claim HPC as being covered by the '798 Patent.

97. By substituting for the general means-function language originally included in the '798 Patent with a more specific HPMC limitation, Glaxo surrendered all equivalents of which it was or should have been aware and prosecution history estoppel barred infringement by the doctrine of equivalents.

98. Summary judgment was therefore granted to IMPAX on August 21, 2002.

99. In granting summary judgment, the Court rejected Glaxo's argument that it did not surrender claims to an HPC equivalent because it did not test HPC as an alternative excipient in the bupropion sustained release tablets. The Court found that one skilled in the art would have known of the substitutability between HPMC and HPC for these purposes.

100. The Court also placed significance on the fact that Glaxo had obtained a patent for a sustained-release formulation comprised of both HPC and HPMC in January 1990. This fact

seriously undermined any claim by Glaxo that it was unaware of HPC as a control release agent at the time it submitted and amended.

101. Glaxo appealed the Northern District of California's ruling in an attempt to preserve its market exclusivity and to dissuade IMPAX from bringing its product to market.

102. On January 29, 2004, the Court of Appeals for the Federal Circuit affirmed the grant of summary judgment in favor of IMPAX.

103. In early 2004, shortly after the Federal Circuit issued its decision in *Glaxo v. IMPAX*, involving facts virtually identical to those presented in the *Eon* lawsuit, Glaxo settled its claims against Eon. IMPAX was the first generic manufacturer to bring its 100 mg. versions of Wellbutrin and Zyban to the market.

104. On January 28, 2004, IMPAX received final FDA approval to enter the market with a 100 mg. version of Wellbutrin and/or Zyban.

**(v) The Excel ANDA and Patent Litigation**

105. In late 2001, Excel submitted an ANDA seeking FDA approval to sell generic versions of Wellbutrin SR and Zyban. The release control excipient used in Excel's version of Wellbutrin SR and Zyban was polyvinyl alcohol ("PVA"). On January 25, 2002, Glaxo brought a patent infringement suit in the Eastern District of Virgina against Excel, claiming that Excel's bupropion sustained release tablets infringed upon the '798 Patent.

106. The Court granted summary judgment to Excel on August 2, 2002. The court found that prosecution history estoppel prevented GSK from capturing PVA as an equivalent of HPMC. The ruling was remanded for additional fact finding by the Federal Circuit on January 29, 2004, before being voluntarily dismissed under Rule 41 of the Federal Rules of Civil Procedure by Glaxo on April 29, 2004.

107. Specifically, the Court found that Excel's generic version of Wellbutrin SR, utilizing PVA as a control release agent, did not literally infringe Glaxo's patent covering HPMC. When Glaxo commenced this action, it was aware that: (i) PVA was recognized as a release controlling excipient at the time the patent application was filed and the patent was issued; and (ii) by narrowing the patent claims during prosecution of the patent, Glaxo abandoned any subject matter that existed between the original and amended claims. Glaxo knew when it commenced the action that no equivalents existed for the invention of the '798 patent that would cover the use of PVA as a release controlling excipient.

**F. The Elimination of Competition in the Sustain Released Buproprion Hydrochloride Market**

108. The FDA's tentative approval letter to Eon in January, 2002 confirmed that Eon's generic product had been otherwise approved to go to market, but was prevented from doing so by legal impediments.

109. At this time, the only legal impediment to Eon's going to market with its 100 mg. generic version of Wellbutrin SR and/or Zyban was the 30-month stay in effect as a result of Defendants' baseless patent infringement suit against it.

110. Glaxo brought other patent infringement lawsuits against potential generic competitors to Wellbutrin SR and Zyban which automatically triggered 30-month stays preventing entry by generic competitors.

111. In the *Andrx* suit, the district court awarded summary judgment in favor of Andrx, and the Court of Appeals for the Federal Circuit reversed. In the *Excel* suit, the Court found on summary judgment that Excel's generic version of Wellbutrin SR, utilizing PVA as a control release agent, did not literally infringe Glaxo's patent covering HPMC. When Glaxo commenced the patent infringement action against Excel, Glaxo was aware, as it was at the time

that it filed the '798 patent application, that: (i) polyvinyl alcohol was recognized as a release controlling excipient; and (ii) by narrowing the patent claims during prosecution, Glaxo abandoned any subject matter that existed between the original and amended claims.

112. In addition to IMPAX, Eon, Andrx, and Excel, Watson was the first company to submit an ANDA seeking FDA approval to sell 100 mg. generic Wellbutrin SR and/or Zyban. Watson later relinquished its first filer status entitling it to a 180 market exclusivity period under the Hatch Waxman Act. Thus, at the time Eon received tentative approval in January 2002, no generic manufacturer held marketing exclusivity rights for the 100 mg. dosage.

113. In November 2003, the 30-month stay having expired, Eon sought and received final approval from the FDA for its generic version of sustained-release bupropion hydrochloride and announced that it would be bringing its product to market.

114. Glaxo sought to further delay Eon from bringing its generic to market by filing a request for an injunction in the United States District Court for the Southern District of New York in November 2003. This action was eventually resolved in favor of Eon, but there was a further delay of the market entry by of Eon.

115. Eon was finally able to bring its generic version of 100 mg. sustained-release bupropion hydrochloride to market on January 27, 2004, approximately two years after it would have come to market if not for Defendants' unlawful acts.

116. The acts and practices of Defendants, as herein alleged, had the purpose and effect of injuring competition by unlawfully delaying the entry of generic Wellbutrin SR and/or Zyban product into the relevant market.

117. Watson's settlement with Glaxo in July 2001 provided that Watson would be permitted to enter the market with a generic version of Wellbutrin SR manufactured by a Glaxo

subsidiary as soon as another generic competitor entered the market. Therefore, but for Glaxo's unlawful filing of its meritless lawsuit against Eon, not only one, but at least two generic competitors to Wellbutrin SR and/or Zyban would have entered the market in July 2001.

118. Defendants have engaged in monopolistic practices concerning Wellbutrin SR and Zyban to avoid a loss in market share and revenues that would inevitably result following the introduction to the market of a competing generic product.

119. If generic competitors had not been unlawfully prevented from entering the relevant market and competing with Defendants, consumers and third-party payors such as Plaintiffs would have been free to substitute a lower-priced generic for the higher-priced brand name drug and would have paid less for Wellbutrin SR and/or Zyban products.

120. Indeed, Defendants have corporate policies to extend and abuse the legitimate range of U.S. patent laws, and Defendants' attempted extension of the Wellbutrin SR/Zyban monopoly is part of the pattern and practices of Defendants. For instance, the Federal Circuit Court of Appeals recently affirmed a District Court verdict that Defendants' patent for the anti-inflammatory prescription drug nabumetone -- which it markets under the brand-name Relafen -- was invalid. *In re '639 Patent Litig.,* 154 F. Supp. 2d 157 (D. Mass. 2001), *aff'd sub nom. Smithkline Beecham Corp. v. Copley Pharm.,* 2002 U.S. App. LEXIS 16594 (Fed. Cir. Aug. 15, 2002). In that case, the District Judge found that SmithKline Beecham had "engaged in a pattern of misrepresentation in its dealings with the PTO so pervasive as to negate any possibility that Beecham's misrepresentations to the PTO were inadvertent "loose language" or otherwise "negligently made." *Id*. at 66. The Court there also found Beecham's witnesses "to be inconsistent, evasive and, many times, implausible." *Id*. at 193-94. The Court further found that Beecham was attempting to persuade the PTO that there was no prior art anticipating its patent,

while evidence before the Court revealed that Defendant's patent department knew this was not the case, and could not believe their success in getting the patent approved, and were happy that they had "put one over on" the PTO. *Id*. at 194.

121. If a generic competitor had been able to enter the relevant market and compete with Defendants, consumers and third-party payors such as Plaintiffs would have been free to substitute a lower-priced generic for the higher-priced brand name drug and the Class would have paid less for Wellbutrin SR and/or Zyban products. Pharmacists generally are permitted, and in many instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payors of prescription drugs (*e.g.*, managed care plans) encourage or insist on the use of generic drugs whenever possible. A generic product can quickly and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year.

122. By preventing generic competitors from entering the market, Defendants injured Plaintiffs and the other Class members in their business or property by causing them to pay more for Wellbutrin SR and/or Zyban products than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiffs and other members of the Class of the benefits of competition that the antitrust laws and applicable state consumer protection laws were designed to preserve.

## INTERSTATE TRADE AND COMMERCE

123. At all times relevant herein, Defendants manufactured and sold substantial amounts of Wellbutrin SR and Zyban in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States as follows:

- Defendants transmitted funds as well as contracts, bills, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Wellbutrin SR and Zyban; and
- Defendants employed, in furtherance of their monopolization and attempt to monopolize, as alleged herein, the United States mails and interstate and international telephone lines as well as means of interstate and international travel.

124. The illegal monopolization and attempt to monopolize the markets for Wellbutrin SR and Zyban as alleged herein have substantially affected interstate and foreign commerce.

## RELEVANT MARKET

125. The relevant product markets are Wellbutrin SR and Zyban and their generic bioequivalents rated "AB" by the FDA. The relevant geographic market is the United States. Defendants' market share in the relevant product and geographic markets was 100%. Since January 2004, when generics were finally able to come to market, Defendants market share eroded due to increasing generic competition.

## COUNT ONE

### For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act For Violations of Section 2 of the Sherman Act

126. Plaintiffs incorporate by reference the preceding allegations.

127. Pursuant to U.S. patent laws, Defendants were given a lawful monopoly over sales of prescription Wellbutrin products, but that monopoly was only lawful so long as the drug, or a method of its use, was fully covered by valid, unexpired patents.

128. Defendants knowingly and willfully engaged in a course of conduct designed to extend, unlawfully, their monopoly power. This course of conduct included, *inter alia,* improperly filing and prosecuting a series of patent infringement actions against companies seeking to market an extended release bupropion hydrochloride product. Defendants' filing and prosecution of these actions was designed to delay the introduction of generic formulations of Wellbutrin SR and/or Zyban into the market and was in violation of Section 2 of the Sherman Act.

129. During the Class Period, Defendants possessed monopoly power in the relevant market. Defendants intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. While obtaining and possessing its unlawful monopoly power over the market for Wellbutrin SR and Zyban Defendants set, maintained and raised the price of Wellbutrin SR and Zyban to artificially high and/or supracompetitive levels.

130. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations. Their injury consists of having paid and continuing to pay higher prices for Wellbutrin SR and/or Zyban products than they would have paid in the absence of those violations. Such injury is of the type antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful. Plaintiffs and members of the Class are likely to purchase Wellbutrin SR and/or Zyban in the future. Injunctive relief is, therefore, appropriate under 15 U.S.C. § 26.

131. Plaintiffs seek injunctive and declaratory relief to enjoin Defendants from engaging in future anticompetitive practices concerning the manufacture, distribution or sale of Wellbutrin SR and Zyban. Plaintiffs do not seek damages under Count I.

**COUNT TWO**

**For Monopolization Under State Law**

132. Plaintiffs incorporate by reference the preceding allegations.

133. As described above, Defendants knowingly and willfully engaged in a course of conduct designed to extend their monopoly power. This course of conduct included, *inter alia*, improperly filing patent infringement actions against generic manufacturers seeking to obtain approval to sell generic versions of Wellbutrin SR and/or Zyban.

134. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Arizona Revised Stat. §§ 44-1401, *et seq.,* with respect to purchases of Wellbutrin SR and Zyban in Arizona by members of the Class.

135. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and Cal. Bus. & Prof. Code §§ 17200, *et seq.* with respect to purchases of Wellbutrin SR and Zyban in California by members of the Class.

136. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in the District of Columbia by members of the Class.

137. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Fla. Stat. §§ 501. Part II, *et seq.,* with respect to purchases of Wellbutrin SR and Zyban in Florida by members of the Class.

138. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Iowa law with respect to purchases of Wellbutrin SR and Zyban in Iowa by members of the Class.

139. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Kansas by members of the Class.

140. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of La. Rev. Stat. §§ 51:137, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Louisiana by members of the Class.

141. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Maine by members of the Class.

142. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Massachusetts by members of the Class.

143. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Mich.CompLaws Ann. §§ 445.771, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Michigan by members of the Class.

144. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Minn. Stat. §§ 325D.52, *et seq*. with respect to purchases of Wellbutrin SR and Zyban in Minnesota by members of the Class.

145. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Miss. Code Ann. §§ 75-21-1, *et seq*., with respect to purchases of Wellbutrin and Zyban in Mississippi by members of the Class.

146. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Neb. Code Ann. §§ 59-801, *et seq*., with respect to

purchases of Wellbutrin and Zyban in Nebraska by members of the Class.

147. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Nev. Rev. Stat. Ann. § 598A., *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Nevada by members of the Class.

148. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1 *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in New Jersey by members of the Class.

149. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of N.M. Stat. Ann. §§ 57-1-1 *et seq*., with respect to purchases of Wellbutrin SR and Zyban in New Mexico by members of the Class.

150. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of New York General Business Law § 340, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in New York by members of the Class.

151. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in North Carolina by members of the Class.

152. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of N.D. Cent. Code § 51-08.1-01, *et seq.,* with respect to purchases of Wellbutrin SR and Zyban in North Dakota by members of the Class.

153. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in South Dakota by members of the Class.

154. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Tenn. Code Ann. §§ 47-25-101, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in Tennessee by members of the Class.

155. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Wellbutrin SR and Zyban in Vermont by members of the Class.

156. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of W.Va. Code §§ 47-18-1, *et seq.,* with respect to purchases of Wellbutrin SR and Zyban in West Virginia by members of the Class.

157. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Wis. Stat. § 133.01, *et seq*., with respect to purchases of Wellbutrin SR and Zyban in Wisconsin by members of the Class.

158. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of paying higher prices for Wellbutrin SR and Zyban prescription drugs than they would have paid in the absence of those violations. This injury is of the type the antitrust and consumer protection laws of the above States and the District of Columbia were designed to prevent and flows from that which makes Defendants' conduct unlawful.

159. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**COUNT THREE**

**For Unfair and Deceptive Trade Practices Under State Law**

160. Plaintiffs incorporate by reference the preceding allegations.

161. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they filed baseless patent infringement actions against Eon and IMPAX and other generic manufacturers in order to prevent the FDA from granting final approval of pending applications of would-be competitors to market generic Wellbutrin SR and Zyban. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and class members were deprived of the opportunity to purchase a generic version of Wellbutrin SR and Zyban, from February 2002 until January 2004, and forced to pay higher prices for Buproprian Hydrochloride SR from January 2004 to present.

162. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq*.

163. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq*.

164. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq*.

165. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq*.

166. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq*.

167. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq*.

168. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq*.

169. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq*.

170. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.

171. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-392, *et seq*.

172. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq*.

173. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.

174. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq*.

175. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq*.

176. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq*.

177. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq*.

178. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq*.

179. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq*.

180. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq*.

181. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq*.

182. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, *et seq*.

183. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Missouri Stat. § 407.010, *et seq*.

184. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq*.

185. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq*.

186. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq*.

187. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq*.

188. Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, *et seq*.

189. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq*.

190. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 *et seq*.

191. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq*.

192. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq*.

193. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq*.

194. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, *et seq*.

195. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq*.

196. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq*.

197. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq*.

198. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq*.

199. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq*.

200. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq*.

201. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq*.

202. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq*.

203. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et seq*.

204. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq*.

205. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq*.

206. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq*.

207. Plaintiffs and members of the class members have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices for Wellbutrin SR and Zyban prescription drugs than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

**COUNT FOUR**

**Unjust Enrichment**

208. Defendants have benefited from the monopoly profits on their sales of Wellbutrin SR resulting from the unlawful and inequitable acts alleged in this Complaint.

209. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Wellbutrin SR and Zyban by Plaintiffs and members of the Class.

210. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

211. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for Wellbutrin SR and Zyban is a direct and proximate result of Defendants' unlawful practices.

212. The financial benefits derived by Defendants rightfully belong to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

213. It would be inequitable for the Defendants to be permitted to retain any of the overcharges for Wellbutrin SR and Zyban derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

214. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by them.

215. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.

216. Plaintiffs and the Class have no adequate remedy at law.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs respectfully request that this Court enter an Order:

A. certifying the Class pursuant to the Federal Rules of Civil Procedure, certifying Plaintiffs as the representatives of the Class, and designating their counsel as counsel for the Class;

B. declaring that Defendants' conduct to be in violation of § 2 of the Sherman Act;

C. declaring the Defendants' conduct to be in violation of the antitrust and/or deceptive practice statutes in the Indirect Purchaser States;

D. enjoining and restraining Defendants' continuing violations of § 2 of the Sherman Act, pursuant to § 16 of the Clayton Act;

E. granting Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

F. granting Plaintiffs and the Class damages as permitted by law;

G. granting Plaintiffs the right of disgorgement;

H. granting Plaintiffs and the Class their costs of prosecuting this action, together with interest and reasonable attorneys' fees, experts' fees and costs; and

I. granting such other relief as this Court may deem just and proper.

**JURY TRIAL DEMAND**

Plaintiffs demand a trial by jury of all issues so triable.

Dated: December 17, 2004

**BOLOGNESE & ASSOCIATES, LLC**

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